

Food and Drug Administration, HHS

§ 868.2380

§ 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989]

§ 868.1975 Water vapor analyzer.

(a) *Identification.* A water vapor analyzer is a device intended to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

Subpart C—Monitoring Devices

§ 868.2025 Ultrasonic air embolism monitor.

(a) *Identification.* An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

(b) *Classification.* Class II (performance standards).

§ 868.2300 Bourdon gauge flowmeter.

(a) *Identification.* A bourdon gauge flowmeter is a device intended for medical purposes that is used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate when the outflow is open to the atmosphere.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 868.2320 Uncompensated thorpe tube flowmeter.

(a) *Identification.* An uncompensated thorpe tube flowmeter is a device intended for medical purposes that is used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device intended for medical purposes that is used to calibrate flowmeters and accurately measure gas flow.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate is outside predetermined limits.

(b) *Classification.* Class II (performance standards).

§ 868.2380 Nitric oxide analyzer.

(a) *Identification.* The nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.